

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Please cancel claims 5, 6, 21-77, and 80-92

Please amend claims 1, 8, 12, 19, 78, and 79 and add new claims 93-100 as follows:

1. (Currently Amended) ~~A drug dosage form comprising a thyroid hormone and at least one pharmaceutically acceptable excipient prepared under conditions of low compression~~ A stable drug dosage form prepared by compression techniques comprising:

a thyroid hormone susceptible to moisture induced degradation, and
particles of at least one pharmaceutically acceptable excipient, each particle having an exterior surface, an interior, equilibrium moisture disposed within the interior of the particles, the thyroid hormone being in contact with the exterior surface of the particles of the at least one pharmaceutically acceptable excipient;

the dosage form prepared by:

admixing the thyroid hormone and the at least one pharmaceutically acceptable excipient; and

compacting the thyroid hormone and the at least one pharmaceutically acceptable excipient into unit dosage forms using compression pressures of less than about 5000 psi/g;

wherein the compression pressure limits the amount of equilibrium moisture available to react with the thyroid hormone at the exterior surface of the particles of the at least one pharmaceutically acceptable excipient.

2. (Original) The drug dosage form of claim 1 comprising a capsule.

3. (Original) The drug dosage form of claim 1 comprising a capsule formed of hydroxypropyl methylcellulose.

4. (Original) The drug dosage form of claim 1 wherein the hormone is contained in solid form within a capsule.

Claims 5-6. Cancelled

5

7. (Original) The drug dosage form of claim 1 wherein the form is subjected to no compression in excess of about 2,000 psi/g.

6

8. (Currently Amended) The drug dosage form of claim 1 wherein the at least one pharmaceutically acceptable excipient is selected from the group consisting of hydroxypropyl methylcellulose, carboxymethyl cellulose, microcrystalline cellulose, amorphous silicon dioxide, magnesium stearate, starch, sodium starch glycolate, or a combination and combinations thereof.

7

9. (Original) The drug dosage form of claim 1 wherein the excipient has a residual moisture content of less than about 10% by weight.

8

10. (Original) The drug dosage form of claim 1 exhibiting improved stability to moisture-induced degradation of the hormone as compared with a tableted form of the hormone.

9

11. (Original) The drug dosage form of claim 1 comprising a unit dosage form.

10

12. (Currently Amended) ~~A drug dosage form comprising levothyroxine and at least one pharmaceutically acceptable excipient prepared under conditions of low compression~~ A stable drug dosage form comprising:

a hydrophobic solid powder;

a thyroid hormone susceptible to moisture induced degradation, treated with said hydrophobic solid powder to substantially water-proof said thyroid hormone; and
at least one pharmaceutically acceptable excipient.

- ¹¹
13. (Original) The drug dosage form of claim ¹⁰12 comprising a capsule.
- ¹²
14. (Original) The drug dosage form of claim ¹⁰12 comprising a capsule formed of hydroxypropyl methylcellulose.
- ¹³
15. (Original) The drug dosage form of claim ¹⁰12 wherein the levothyroxine is contained in solid form within a capsule.
- ¹⁴
16. (Original) The drug dosage form of claim ¹⁰12 wherein the form is subjected to no compression in excess of about 10,000 psi/g.
- ¹⁵
17. (Original) The drug dosage form of claim ¹⁰12 wherein the form is subjected to no compression in excess of about 5,000 psi/g.
- ¹⁶
18. (Original) The drug dosage form of claim ¹⁰12 wherein the form is subjected to no compression in excess of about 2,000 psi/g.
- ¹⁷
19. (Currently Amended) The drug dosage form of claim ¹⁰12 wherein the at least one pharmaceutically acceptable excipient is selected from the group consisting of hydroxypropyl methylcellulose, carboxymethyl cellulose, microcrystalline cellulose, amorphous silicon dioxide, magnesium stearate, starch, sodium starch glycolate, or a combination and combinations thereof.
- ¹⁸
20. (Original) The drug dosage form of claim ¹⁰12 wherein the excipient has a residual moisture content of less than about 10% by weight.

Claims 21-77. Cancelled

18
78. (Currently Amended) A method ~~[[of]]~~ for administering a thyroid hormone to a patient comprising:

~~providing a unit dose of thyroid hormone which has not been processed employing high compression~~ comprising:

a hydrophobic solid powder;

a thyroid hormone susceptible to moisture induced degradation, treated with said hydrophobic solid powder to substantially water-proof said thyroid hormone; and

at least one pharmaceutically acceptable excipient;

said stable dosage form prepared by:

admixing said thyroid hormone with said hydrophobic powder, each particle of thyroid hormone being substantially enveloped by said hydrophobic powder,

adding said at least one pharmaceutically acceptable excipient to said admixture of said thyroid hormone and said hydrophobic powder;

compacting said enveloped thyroid hormone, said at least one pharmaceutically acceptable excipient, and said hydrophobic powder using a compression pressure of less than 5000 psi/g.

20
79. (Currently Amended) ~~A method of administering levothyroxine to a patient comprising providing a unit dose of thyroid hormone which has not been processed employing high compression~~ The method for administering a thyroid hormone to a patient of claim 78 19
wherein the thyroid hormone is levothyroxine.

Claims 80-92. Cancelled

19
21 93. (New) The drug dosage form of claim 12 wherein said pharmaceutically acceptable excipient is treated by admixing said thyroid hormone and said hydrophobic powder, each particle of thyroid hormone being substantially enveloped by said hydrophobic powder.

10
22 94. (New) The drug dosage form of claim 12 wherein said drug dosage form is prepared by:

admixing said thyroid hormone with said hydrophobic powder, each particle of thyroid hormone being substantially enveloped by said hydrophobic powder,

adding said at least one pharmaceutically acceptable excipient to said admixture of said thyroid hormone and said hydrophobic powder;

compacting said enveloped thyroid hormone, said at least one pharmaceutically acceptable excipient, and said hydrophobic powder using a compression pressure of less than 5000 psi/g.

23 10
95. (New) The drug dosage form of claim 12 wherein said at least one pharmaceutically acceptable excipient comprises less than 10 percent by weight, based on the weight of said pharmaceutically acceptable excipient, of equilibrium moisture, said moisture disposed within the interior bulk of each particle of said at least one pharmaceutically acceptable excipient.

24 10
96. (New) The drug dosage form of claim 12 wherein said hydrophobic powder comprises magnesium stearate, antioxidants, or combinations thereof.

25 10
97. (New) The drug dosage form of claim 12 wherein said drug dosage form comprises from about 0.5 weight percent to about 5.0 weight percent, based on the weight of the drug dosage form, of hydrophobic powder.

26 10
98. (New) The drug dosage form of claim 12 comprising a tablet.

27 10
99. (New) The drug dosage form of claim 12 wherein the decrease in weight percent of thyroid hormone after being stored at 60°C and a relative humidity of 75% for 5 days is less than 9.5 percent.

28
100. (New) A method for preparing a stable drug dosage form comprising:
a hydrophobic solid powder;

a thyroid hormone susceptible to moisture induced degradation, treated with said hydrophobic solid powder to substantially water-proof said thyroid hormone; and

at least one pharmaceutically acceptable excipient;

the method comprising the steps of:

admixing said thyroid hormone with said hydrophobic powder, each particle of thyroid hormone being substantially enveloped by said hydrophobic powder,

adding said at least one pharmaceutically acceptable excipient to said admixture of said thyroid hormone and said hydrophobic powder;

compacting said enveloped thyroid hormone, said at least one pharmaceutically acceptable excipient, and said hydrophobic powder using a compression pressure of less than 5000 psi/g.